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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/721,877	11/26/2003	Ken-Yuan Chang	CHAN3233/EM	6012
23364	7590	03/10/2006	EXAMINER	
BACON & THOMAS, PLLC 625 SLATERS LANE FOURTH FLOOR ALEXANDRIA, VA 22314			ROBERTSON, JEFFREY	
			ART UNIT	PAPER NUMBER
			1712	

DATE MAILED: 03/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/721,877	Applicant(s) CHANG ET AL	
	Examiner Jeffrey B. Robertson	Art Unit 1712	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 05 January 2006.  
 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.  
 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-8 and 10 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
 6) ☒ Claim(s) 1,4-7 and 10 is/are rejected.  
 7) ☒ Claim(s) 2,3 and 8 is/are objected to.  
 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.  
 10) ☒ The drawing(s) filed on 26 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) ☐ All b) ☐ Some \* c) ☐ None of:  
 1. ☐ Certified copies of the priority documents have been received.  
 2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Claim Objections***

1. Claims 6 and 7 are objected to because of the following informalities: for claims 6 and 7, these claims fail to identify the type of molecular weight, i.e. number average or weight average molecular weight, set forth in the claim. Appropriate correction is required.

### ***Prior Art Rejections***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1, 4-7, and 10 are rejected under 35 U.S.C. 102(e) as being anticipated by Seo et al. (U.S. Patent No. 6,616,941).

For claims 1 4, and 7, Seo teaches that PLGA/PEG copolymers are prepared where R<sub>3</sub> is methyl and the molecular weight of the hydrophilic block is 2000. These block copolymers have the same structure as set forth in formula (I) because methoxylated polyethylene glycol is used so that diblock copolymers are formed. See Example 4. For claim 6, Seo teaches that the molecular weight of the hydrophobic portion is preferably between 1,000-10,000, significantly overlapping the range set forth

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by applicant. Col. 4, lines 7-10. For claims 5 and 10, it is the examiner's position that the properties claimed by applicant would be inherent to the composition since the polymers claimed are the same as those disclosed in the Seo reference.

For claim 1, Seo is silent on the LCST properties of the polymer. However, it is noted that the polymer of Example 4 contains x:y:z values of 8:18:45. (Calculations: mPEG MW=2000, MW of repeat unit ~44, number of repeat units ~45, 20 grams used  $20\text{g}/2,000=0.01$  mols; lactide mw=144, 2 units result from each lactide molecule, 12.5 grams used,  $12.5/144=0.09$  mols; glycolide mw=116, 2 units result from each glycolide molecule, 4.5 grams used,  $4.5/116=0.04$  mols; 0.01/0.01 mPEG: 0.09/0.01x2 lactide: 0.04/0.01x2 glycolide). The examiner's position is that since the polymer contains amounts of polymer units within applicant's given ranges in the specification page 4, lines 8-20, the polymer would have LCST properties within applicant's claimed range.

### ***Response to Arguments***

4. Applicant's arguments filed 1/5/06 have been fully considered but they are not persuasive. Regarding the claim objections as set forth above, applicant argues that one of ordinary skill in the art would understand what is meant by molecular weight without the need to specify whether the molecular weight is weight average or number average. The examiner disagrees. Due to the wide variations that may be present between weight average and number average molecular weight, the type of molecular weight should be specified. It is noted that applicant has not identified the type of molecular weight in the response.

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Applicant argues that the LCST is affected by the percentage of hydrophilic and hydrophobic units of the block copolymer. Applicant argues that none of the prior art references even mention LCST or its significance in providing a suitable block copolymer for a drug release system. Applicant argues that the LCST properties are not inherent to all block copolymers. Applicant also argues that none of the prior art references set forth the percentages required by applicant to achieve the specific LCST properties claimed. The examiner disagrees. As further detailed above, the percentages and amounts of the units of Example 4 of the Seo reference appear to be within the ranges set forth by applicant to achieve the LCST properties claimed. Therefore, applicant's arguments are not persuasive and the above rejection has been continued.

#### ***Allowable Subject Matter***

5. Claims 2, 3, and 8 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

#### ***Conclusion***

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not


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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey B. Robertson whose telephone number is (571) 272-1092. The examiner can normally be reached on Mon-Fri 7:00-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Randy P. Gulakowski can be reached on (571) 272-1302. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Jeffrey B. Robertson  
Primary Examiner  
Art Unit 1712

JBR